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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,964	01/22/2004	Kevin Tait	SW-045AX	6339
<div>7590 01/11/2008</div> <div>WEINGARTEN, SCHURGIN, GAGNEBIN & HAYES LLP</div> <div>Ten Post Office Square</div> <div>Boston, MA 02109</div>				
			<div>EXAMINER</div> <div>SCHLIENTZ, LEAH H</div>	
			<div>ART UNIT</div> <div>1618</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE</div> <div>01/11/2008</div>	<div>DELIVERY MODE</div> <div>PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/762,964

Applicant(s)

TAIT, KEVIN

Examiner

Leah Schlientz

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-19 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/800,076.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/02/2007 has been entered.

Status of Claims

Claim 1 has been amended. New claim 19 has been added. Claims 1 – 19 pending and are examined herein on the merits for patentability.

Response to Arguments

Applicant's arguments, see pages 9 – 12 of the Response, with respect to the rejection of claims 1 – 4, 6 – 8 and 10 under 35 USC 102(b) as being anticipated by Brown (US 3,236,735), have been fully considered. The rejection has been WITHDRAWN as being overcome by amendment, because the formulations of Brown comprise ionic dispersant.

Applicant's arguments, see pages 12 – 13 of the Response, with respect to the rejection of claims 1 – 4, 6 – 8 and 10 – 16 under 35 USC 103(a) as being unpatentable over Brown (US 3,236,735) in view of Queille (US 4,120,946), have been fully considered. The rejection has been WITHDRAWN as being overcome by amendment.

Applicant's arguments, see pages 13 – 15 of the Response, with respect to the rejection of claims 1 – 10 and 12 – 16 under 35 USC 103(a) as being unpatentable over Brown (US 3,236,735) in view of Ruddy (US 5,466,440) and Weaver (US 3,935,099), have been fully considered. The rejection has been WITHDRAWN as being overcome by amendment.

Applicant's arguments, see pages 13 – 15 of the Response, with respect to the rejection of claims 1 – 4, 6 – 8, 10 and 12 – 16 under 35 USC 103(a) as being unpatentable over Brown (US 3,236,735) in view of Kaufman (US 6,331,116), have been fully considered. The rejection has been WITHDRAWN as being overcome by amendment.

Claim Objections

Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

New Grounds for Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 4, 6 – 10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller *et al.* (DD 238530) in view of Brown (US 3,236,735).

Mueller discloses a stabilized barium sulfate suspension of valuable and easily obtainable as well as physiologically tolerated raw materials comprising barium sulfate, alumina and water up to concentrations of 0.5 – 2% of barium sulfate and 3 – 6% of alumina. As alumina is preferably used a suitable bentonite. Adding the usual sweeteners and aromatic substances is advantageous for the application. The physiological innocuousness and excellent suitability as radiological contrast agent were demonstrated by means of animal testing and clinical trials (see translation pages 3 –

4). For example, a composition comprising bentonite, water, saccharose, barium sulfate, and vanillin is exemplified.

Accordingly, Mueller teaches a radiological composition comprising barium sulfate and a flocculant (bentonite) and a viscosity modifier (saccharose). The formulation lacks ionic dispersant. However, Mueller does not specifically teach that his formulation is a solid.

Brown teaches formulations comprising barium sulfate for use as x-ray contrast media (column 1, lines 10 – 13). The formulations may be provided as a liquid, or a dry composition containing both barium sulfate and additives is particularly convenient and economical to store and ship. Such a composition is primarily used for the preparation of suspensions having a predetermined barium sulfate content, since the concentrations of the additives in the aqueous medium of the suspension are somewhat critical while the proportions of barium sulfate and additives in the dry composition are necessarily fixed. Such a dry composition may be prepared by combining the required proportions of barium sulfate and additives using a convenient amount of water, and then removing the water by drying, as for example by spray- or film-drying the initial suspension. The resulting dry product consists of barium sulfate particles coated with the additives. The final suspension is then easily prepared as needed by stirring the dry composition into the required amount of water. A dry composition may also be prepared by blending the dry ingredients in the conventional manner, but there is some advantage to using a wet process, as outlined above, since a more even distribution of all ingredients is thereby obtained. If preferred, a dry composition may also be prepared consisting essentially of

the additives. This composition may then be mixed with an appropriate proportion of barium sulfate and of water to form the final barium sulfate containing composition.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the formulation of Mueller in the form of a solid. One would have been motivated to do so, and would have had a reasonable expectation of success in doing so, because Brown specifically teaches that dry formulations comprising barium sulfate intended for use as contrast media are particularly convenient and economical to store and ship (column 2, lines 57 – 59). One would have had a reasonable expectation of success in doing so because Brown teaches a variety of methods of preparation of such dry compositions from aqueous solution, such as combining the required proportions of barium sulfate and additives using a convenient amount of water, and then removing the water by drying, as for example by spray- or film-drying the initial suspension.

Regarding claim 1, it is noted that the functional recitation wherein "0.25 g. of said stool marker formulation is diluted with water to 50 ml and titrated against 3.0% w/v ferrous sulfate at pH 5.0-5.55 has a flocculation resistance of less than 5 ml," has not been given patentable weight to distinguish over Mueller. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same functional characteristics of the claimed product. The claims are descriptive and thus would be an inherent property of the claimed composition. In the absence to the contrary, the burden is upon the applicant to prove that the claimed products are

functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). Since Mueller teaches a composition comprising the same components as those claimed (i.e. barium sulfate, bentonite, and the absence of ionic dispersant), it is interpreted, absent evidence to the contrary, that the composition would inherently possess the same claimed flocculation properties.

It is further noted that the recitation of the intended use of the formulation as a stool marker has not been given patentable weight to distinguish over Mueller, in view of Brown, because the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Regarding claims 2 – 4, the claims are drawn to compositions and not methods, there is no administered dose, and the compositions disclosed by the prior art would be capable of providing the doses as claimed.

Regarding claim 8, it is noted that a clay may be representative of an anti-caking agent. Since the formulation of Mueller comprises a clay, bentonite, it would have been obvious to one of ordinary skill in the art to include an additional clay. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be

useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Regarding claim 9, it is noted that the instant claims are product claims, not process of making or using claims. The limitation wherein the formulation is treated with high shear stirring and sonification prior to administration appears to be a product-by-process type limitation. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claims 1 – 10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller *et al.* (DD 238530) in view of Brown (US 3,236,735) as applied to claims 1 – 4, 6 – 10 and 19 above, in further view of Ruddy *et al.* (US 5,466,440).

Mueller and Brown do not teach the particle size of the barium sulfate.

Ruddy teaches barium sulfate compositions that also comprise a smectite clay (montmorillonite) which are in particle sizes which encompass those claimed, (column 5, lines 50+ and claim 1). Ruddy teaches the use of high shear provides the advantages of decreasing the processing time (column 12, lines 30+).

It would have been obvious to one of ordinary skill in the art to utilize barium sulfate including particles within the claimed size in the formulation of Mueller, because both the formulations of Mueller and Ruddy are intended for use as radiographic contrast media, and one having ordinary skill would have been motivated to utilize particles having the standard particle size when performing such endeavors.

Claims 1 – 10 and 12 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller *et al.* (DD 238530) in view of Brown (US 3,236,735) as applied to claims 1 – 10 and 19 above, in further view of Vining (US 6,083,162).

Mueller and Brown do not teach a method of visualizing the colon via administering the formulation and manipulating data to determine the portion of data due to marked stool to thereby provide a representation of the colon.

Vining teaches methods for generating interactive, three-dimensional renderings of a patient's colon set forth in Figure 1. The patient can be fed a low residue diet combined with a contrast agent (such as a low density barium, for example, 1.5% W/V barium) for about three days. Such a procedure may serve to homogeneously opacify any retained stool so that the image of the feces can then be subtracted from the final

display, or at least from selected images, using image processing techniques (column 8, lines 1 – 20). The technique should allow for the discovery of polyps of 1 cm or greater in size in the colon (column 2, line 12), and is performed via use of a helical CT scanner (column 2, line 29).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize the barium sulfate formulation of Mueller in the methods of Viking. One would have been motivated to do so, and would have had a reasonable expectation of success in doing so because both teach similar barium compositions for use in radiographic imaging and because Mueller teaches his formulation to have advantages such as being economical. Furthermore, it would have been obvious to optimize the step of administering multiple doses or the time period of administration as a matter of routine experimentation in order to identify the dosage regimen with desirable effectiveness.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

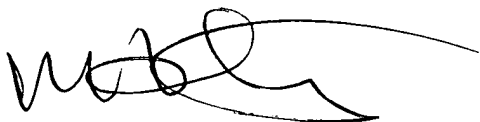
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LHS



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER